EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Institutions (non-hospital) questionnaire	72	9	14.24	128
Pharmacies questionnaire	7,760	9,040	14.24	128,730
Subtotal for the MEPS–MPC	39,813	20,077	na	285,965
Grand Total	92,613	82,767	na	1,512,181

*Based upon the mean of the average wages for Healthcare Support Workers, All Other (31–9099) and All Occupations (00–0000), Occupational Employment Statistics, May 2007 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#b29–0000.*

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost of this information collection. The cost associated with the design and data collection of the MEPS–HC and MEPS–MPC is estimated to be $47.6 million in each of the next three fiscal years.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost Component	Total cost (millions)	Annualized cost (millions)
Sampling Activities	$2.79	$0.93
Interviewer Recruitment and Training	8.52	2.84
Data Collection Activities	86.7	28.9
Data Processing	21.39	7.13
Production of Public Use Data Files	19.53	6.51
Project Management	3.93	1.31
Total	142.8	47.6

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 16, 2009.

Carol M. Clancy,

Director.

[FR Doc. E9–24305 Filed 10–8–09; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2009–E–0073 and FDA–2009–E–0015]

Determination of Regulatory Review Period for Purposes of Patent Extension; ENTEREG; U.S. Patent Nos. 5,250,542 and 5,434,171

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ENTEREG and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of patents which claim that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug

products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ENTEREG (alvimopan). ENTEREG is a peripherally acting μ-opioid receptor antagonist indicated to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for ENTEREG (U.S. Patent Nos. 5,250,542 and 5,434,171) from Eli Lilly and Company, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 26, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ENTEREG represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ENTEREG is 5,305 days. Of this time, 3,879 days occurred during the testing phase of the regulatory review period, while 1,426 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: November 12, 1993. The applicant claims November 11, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 12, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: June 25, 2004.* FDA has verified the applicant's claim that the new drug application (NDA) 21–775 was submitted on June 25, 2004.

3. *The date the application was approved*: May 20, 2008. FDA has verified the applicant's claim that NDA 21–775 was approved on May 20, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,827 days of patent term extension for U.S. Patent No. 5,250,542 and 1,826 days of patent term extension for U.S. Patent No. 5,434,171.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by December 8, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 7, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 31, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–24457 Filed 10–8–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0448]

Draft Guidance for Industry and Food and Drug Administration Staff; the Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13." This document is intended to provide guidance to mammography facilities and their personnel. It represents FDA's current thinking on the final regulations implementing the Mammography Quality Standards Act of 1992 (MQSA). This guidance document updates previous guidance. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 7, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled "The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number